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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,827	09/12/2003	Andreas Hartlep	SCHWP0177USA	7728

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RENNER, OTTO, BOISSELLE & SKLAR, LLP
Nineteenth Floor
1621 Euclid Avenue
Cleveland, OH 44115-2191

EXAMINER	
CHAO, ELMER M	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

C.

Office Action Summary	Application No.	Applicant(s)	
	10/661,827	HARTLEP ET AL.	
	Examiner	Art Unit	
	Elmer Chao	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/12/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Non-patent literature*.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

On October 26, 2005, the USPTO published Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility. See: http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

This guideline details a procedure for determining patent eligible subject matter. As to claim 1, the first step in this process is whether the claims fall within one of the enumerated categories. In the immediate application, the claims are drawn to a process - a "method for identifying advantageous and non-advantageous tissue" - and meets this step. However, the analysis does not end here. The next step is whether a judicial exception (abstract ideas, laws of nature, natural phenomenon) is provided in the claim. In the immediate application, claim 1 clearly includes one of the judicial exceptions in that "capturing and evaluating the data and determining information are nothing more than abstract ideas. While abstract ideas alone are not eligible, the claim as a whole must be analyzed to determine whether it is for a particular application of the

abstract idea. For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomena. *To satisfy the requirement of a practical application, the claimed invention must:*

(1) transform an article or physical object to a different state or thing; if no transformation, then

(2) the claimed invention must produce a useful, concrete, and tangible result.

Regarding (1) above, the claims do not provide a transformation or reduction of an article to a different state or thing. "Capturing and evaluating" captured anatomical data with computer assistance does not transform an article or physical object to a different state or thing. Similarly, "Determining" infusion distribution information does not transform an article or physical object to a different state or thing. Accordingly, one must then consider whether the claimed invention produces a useful, concrete, **and** tangible result.

(1) Useful Result

For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of the invention has to be (i) specific, (ii) substantial and (iii) credible. See MPEP 2107. It can be argued that the claim does not provide a useful result in that the claim does not actually solve a problem. Simply determining infusion distribution information thereafter does not appear to be useful.

(2) Tangible Result

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real world result.

Regarding the tangible result requirement, the claim clearly does not provide a practical application for reasons similar to that discussed above. For example, once evaluated and determined, how is this then applied?

(3) Concrete Result

Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process which requires a particular skill, to determine whether the process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary skilled artisan.

Regarding the concrete result requirement, the claim does not provide a result that can be assured in that the result cannot be substantially repeatable and the process cannot substantially produce the same result again. Simply capturing and evaluating data or determining infusion distribution information does not produce any concrete results.

In view of the above analysis, applicant's claim 1 is a process which includes a judicial exception therein. Upon review of the claim as a whole, there is no transformation nor does the claim produce a useful, concrete, and tangible result. Accordingly, the claim is non-statutory under 35 U.S.C. 101.

It is noted that the subject matter of **claims 2-17** also do not remedy the statutory requirement.

Furthermore, **claims 16 and 17** do not fall into any of the enumerated categories of statutory subject matter. A "program" per se is not considered a process, machine, manufacturer, or composition of matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

MPEP 2164.01 sets forth the "Test of Enablement." Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the

subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies , Inc ., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

UNDUE EXPERIMENTATION

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. In re Certain Limited-Charge Cell Culture Microcarriers, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), aff 'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). 2164.01(a)

Undue Experimentation Factors

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). In Wands, the court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts. In re Wands, 858 F.2d at 736-40, 8 USPQ2d at 1403-07. The Court held that the specification was enabling with respect to the claims at issue and found that "there was considerable direction and guidance" in the specification; there was "a high level of skill in the art at the time the application was filed;" and "all of the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406. After considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." Id., 8 USPQ2d at 1407. It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention

without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. These factual considerations are discussed more fully in MPEP § 2164.08 (scope or breadth of the claims), § 2164.05(a) (nature of the invention and state of the prior art), § 2164.05(b) (level of one of ordinary skill), § 2164.03 (level of predictability in the art and amount of direction provided by the inventor), § 2164.02 (the existence of working examples) and § 2164.06 (quantity of experimentation needed to make or use the invention based on the content of the disclosure).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kucharczyk et al. (U.S. 6,026,316).

Regarding **claims 1, 16, 17**, Kucharczyk '316 discloses a method for identifying advantageous and non-advantageous infusion regions in a tissue (Fig 7, 4th box down), said method comprising: capturing structural anatomical data (Fig 7); evaluating the

captured anatomical data with computer assistance (the methods of Fig 7 inherently require computer assistance); and based on the evaluating step, determining infusion distribution information (Fig 7, 4th box down).

Regarding **claim 2**, Kucharczyk '316 discloses the method as set forth in claim 1, wherein evaluating the captured anatomical data includes simulating a distribution of an infusion at a plurality of regions in the tissue (Fig 7, last box, "Repeat drug delivery as necessary"; also claim 8, "...delivery device relocated to improve delivery of material to desired location," which is equivalent to simulating the delivery distribution in a plurality of regions).

Regarding **claim 3**, Kucharczyk '316 discloses the method as set forth in claim 1, wherein the determined infusion distribution information includes direction information and velocity information relating to infusion regions in the tissue (C8, L61-65, "...distribution kinetics..."; C9, L56-60, "...spatial (direction) distribution kinetics..."; C7, L7-10); Fig 11, graph shows different areas and the relative speeds of diffusion in the areas).

Regarding **claims 4, 10, and 11**, Kucharczyk '316 discloses the method as set forth in claim 1, wherein the anatomical data is evaluated two-dimensionally with respect to the distribution information which it contains, and wherein a number of two-dimensional data sets on the functional or structural anatomical data are combined to obtain three-dimensional information (C22, L63-65; "...echo weighted scans...nominal voxel.").

Regarding **claims 5 and 12**, Kucharczyk '316 discloses the method as set forth in claim 1, wherein the anatomical data is captured and evaluated three-dimensionally with respect to the distribution information which it contains (Fig 7, 2nd box down; C23, L45-46).

Regarding **claim 6**, Kucharczyk '316 discloses the method as set forth in claim 1, further comprising: evaluating the anatomical data over a period of time with respect to the distribution information; And making adjustments in the distribution information, said adjustments being responsive to structural conditions which have changed over the period of time (Fig 7, boxes 5-7 down from the top).

Regarding **claims 7 and 8**, Kucharczyk '316 discloses the method as set forth in claim 3, further comprising: identifying regions of rapid diffusion (Fig 10, "...along fibers, rapid transport"), determining isotropy and anisotropy of flow directions in the regions in the tissue (Fig 10, "...anisotropic...isotropic..."; C23, L41-50).

Regarding **claim 9**, Kucharczyk '316 discloses the method as set forth in claim 1, further comprising: calculating a distribution volume for an infusion fluid from the functional or structural anatomical data (C7, L6-11, "..signal intensity within MR images ... are indicative of ... delivery volumes.").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk '316, in view of Gillies et al. (U.S. 6,272,370).

Regarding **claims 13, 14, 18, and 19**, Kucharczyk '316 discloses all of the above limitations. Kucharczyk '316 does not disclose the infusion at the selected point being planned using stereotactic planning and navigation. However, Gillies '370 teaches the use of stereotactics in combination with magnetic resonance imaging in the planning and navigation for drug delivery (abstract). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Kucharczyk '316 to use Gillies' '317 method to perform the infusion after the infusion site has been selected. Such a modification would produce a method of drug delivery that is more accurate and less damaging to other areas around the target area (C10, L1-9).

Regarding **claim 15**, Kucharczyk '316 uses the acquired anatomical tissue data (Fig 7, 2nd box down) combined with distribution information (Fig 7, 4th box down) for planning the navigation (claim 8; Fig 7, last box down).

Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk '316, in view of Gillies '370, and further in view of Strommer et al. (U.S. 6,233,476 B1). Kucharczyk '316 and Gillies '370 disclose all of the above limitations. Kucharczyk '316 and Gillies '370 do not explicitly disclose the imaging device, processor, and the medical planning and navigation system being connected together. However, Strommer '476 teaches a medical positioning system in which the

processor, imager, and navigation system are all connected together (C4, L46-55). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Kucharczyk's '316 and Gillies' '317 apparatus wherein the imaging device, the processor, and the medical planning and navigation system are connected to each other. Such a modification would allow for the location of the catheter or infusion device to be located and superimposed on the image obtained from the imager (C4, L46-55). Kucharczyk '316 does imply the necessity of the processor, imager, and navigation system to all be connected together because of the method of "superimposing drug delivery map on anatomic map of target tissue..." (Fig 7, 8th box down).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Howard et al. (U.S. 6,216,030); Elsberry et al. (U.S. 5,735,814); Furhang E.E. et al. (Medical Physics, American Institute of Physics; September 2001; Pages 1857-1874).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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